Heart Disease Therapy Cleared for Phase 2 Clinical Trial to be Funded by Stem Cell Agency

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San Francisco, CA – A stem cell therapy aimed at treating patients who have had a heart attack has been given approval to begin a Phase 2 clinical trial funded by California's stem cell agency, the California Institute for Regenerative Medicine (CIRM).

The treatment, developed by Capricor Therapeutics, Inc., uses unrelated donor-derived stem cells, called cardiosphere-derived cells, that are then infused into a patient's artery with the aim of reducing scarring caused by heart attacks. In a Phase 1 clinical trial designed to test the safety of the therapy, the cells were introduced into 14 patients and were found to be safe.

"This is really encouraging news and marks a potential milestone for the use of stem cells to treat heart disease," says Alan Trounson, Ph.D., President of the stem cell agency. "Funding this type of work is precisely what our Disease Team Awards were designed to do, to give promising treatments up to $20 million dollars to develop new treatments for some of the deadliest diseases in America."

The National Heart Lung and Blood Institute (NHLBI) Gene and Cell Therapy (GST) gave Capricor approval to move into the next phase after reviewing safety data and determining that it met all the required goals. CIRM independently reviewed the safety from the Phase 1, as well as other aspects of the Phase 2 clinical trial design and operations, and gave approval to move forward into the CIRM funded Phase 2 component of the study.

"This is a highly significant announcement for us at CIRM as it's the first time we have funded a therapy into a Phase 2 clinical trial," says Jonathan Thomas, Ph.D., J.D., Chair of the governing Board of the stem cell agency. "Heart disease claims around 600,000 American lives every year, so clearly there is a huge need for new approaches and more effective therapies. We are hopeful this is the first of many treatments to turn the tide against this disease, and that this will be the first of many projects we are funding to get to a Phase 2 trial."

Capricor CEO, Dr. Linda Marbán stated, "Meeting the safety endpoints in the Phase 1 portion of the trial is a giant leap forward for the field and for Capricor Therapeutics. By moving into the Phase 2 portion of this trial, we can now attempt to replicate the results in a larger population."

The next phase will involve an estimated 300 patients who have had heart attacks, and they will be evaluated in a double-blind, randomized, placebo-controlled trial. This will be further broken down into two groups: one will include patients 30-90 days post attack, the second will be 91 days to one year after the incident.

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided $3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research.

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